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Single-use duodenoscopes compared with reusable duodenoscopes in patients carrying multidrug-resistant microorganisms: a break-even cost analysis

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ABSTRACT

Background and study aims Single-use duodenoscopes can prevent transmission of microorganisms through contaminated reusable duodenoscopes. Concerns regarding their economic and environmental impact impede the transition to single-use duodenoscopes. This study investigated the costs associated with two scenarios in which single-use duodenoscopes are used in patients carrying multidrug-resistant microorganisms (MDROs).

Methods Break-even costs for single-use duodenoscopes were calculated for two scenarios in which patients were screened for MDRO carriage before undergoing endoscopic retrograde cholangiopancreatography (ERCP). Only direct costs related to the endoscopy were taken into consideration. In Scenario 1, patients were screened through microbiological culturing with a lag time in receiving the test result. In Scenario 2, screening was performed using GeneXpert analysis providing a rapid read-out. Calculations were performed using data from a Dutch tertiary care center and also with US healthcare data.

Results In the Dutch situation, single-use duodenoscopes needed to be priced at a maximum of €140 to €250 to break-even. In the US analyses, break-even costs varied widely, depending on the duodenoscope-associated infection costs used, ERCP volume, and infection risk. The break-even costs in Scenario 1 ranged between $78.21 and $2,747.54 and in Scenario 2, between $248.89 and $2,209.23.

Conclusions This study showed that a crossover scenario in which single-use duodenoscopes are only used in patients carrying MDROs could be an economically viable alternative to a complete transition to single-use duodenoscopes. In the Dutch setting, single-use duodenoscopes need to be priced much lower than in the United States to reach a per-procedure cost that is comparable with a scenario using reusable duodenoscopes exclusively.

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Introduction

Reusable duodenoscopes are difficult to clean and can remain contaminated with microorganisms despite strict adherence to cleaning and disinfection protocols. This has led to numerous duodenoscope-associated infections (DAIs) worldwide [1,2]. Due to detection and reporting bias, the true DAI risk remains unclear. For the Netherlands, we calculated a bare minimum risk of 0.01% per endoscopic retrograde cholangiopancreatography (ERCP) procedure, but this likely represents the tip of the iceberg due to under-detection and underreporting [3]. Attempts to completely eliminate duodenoscope contamination with more elaborate reprocessing protocols, low-temperature sterilization, strict audit and surveillance programs and adjustments in duodenoscope designs have not resulted in a zero contamination rate [4–6].

Recently, two types of single-use duodenoscopes (SUDs) have been cleared by the Food and Drug Administration (FDA) and introduced to the market [7]. SUDs are the ultimate solution to eliminate DAIs. However, apart from environmental concerns, the use of SUDs may substantially increase the costs of ERCP procedures. In recent articles, discussion is ongoing to define the patient risk groups for whom the use of SUDs is most likely to be beneficial [8–10].

Most recent outbreaks are based on the transmission of multidrug-resistant organisms (MDROs) through contaminated duodenoscopes [11]. Whether this is based on a higher virulence of MDROs or that outbreaks with susceptible microorganisms go by unnoticed is unclear. In an attempt to prevent these MDRO outbreaks and the spread of MDROs, a strategy could be adopted in which known MDRO carriers are treated with SUDs and non-carriers with reusable duodenoscopes [10].

In the current analysis, we compare the costs of our current ERCP practice in which we only use reusable duodenoscopes with crossover scenarios in which only patients who are proven MDRO-negative are treated with a reusable duodenoscope and all other patients are treated with an SUD. For that it is assumed that patients are screened for MDRO carriage prior to the ERCP procedure. When no rapid test read-out is available and there is an urgent indication to perform an ERCP, the application of a SUD is simulated. This study aimed to investigate the costs for SUDs at which these crossover scenarios break even economically with the current situation in which only reusable duodenoscopes are used. In addition to the analyses done in our center located in the Netherlands, separate cost analyses comparing the same strategies were performed for the US situation, based on details found in a public database and international literature [12,13].

Methods

Setting

This study was performed in the Erasmus Medical Centre (Rotterdam, the Netherlands), a 1,125-bed tertiary care center, performing approximately 900 ERCP procedures per year.

Currently, eight reusable duodenoscopes are used in our center, with models from two manufacturers (Pentax Medical, Dodewaard, the Netherlands and Olympus, Zoeterwoude, the Netherlands). Reprocessing is performed by a dedicated staff. Cleaning and disinfection takes place in automated endoscope reprocessors and afterwards, the duodenoscopes are placed in an automated drying and storage cabinet (both Wassenburg, Dodewaard, the Netherlands). Surveillance culturing of the duodenoscopes is performed monthly.

We analyzed two crossover scenarios in which selected patients were treated with SUDs instead of regular reusable duodenoscopes, depending on MDRO carrier status (▶ **Fig. 1** and ▶ **Fig. 2**):

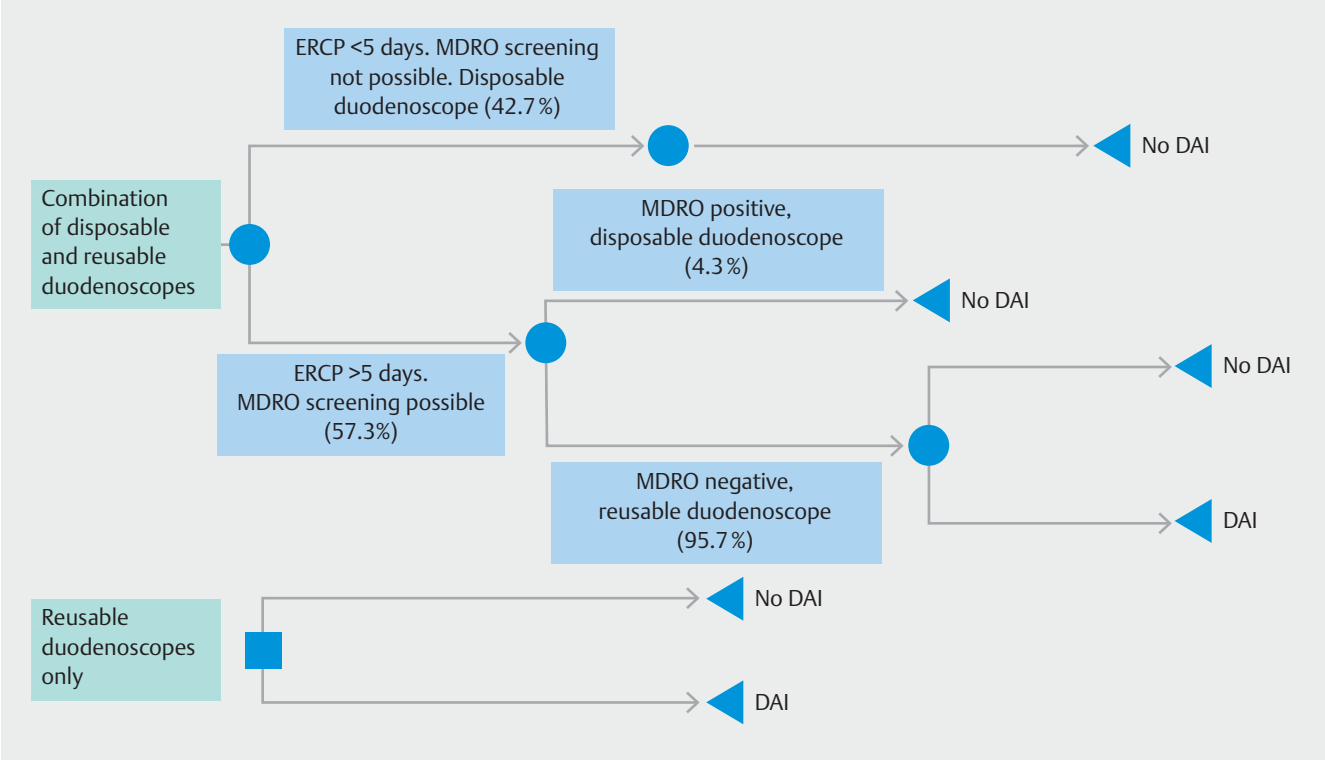
For crossover Scenario 1, in every patient scheduled for an elective ERCP, MDRO screening was carried out via rectal swab cultures. This screening was done either in the outpatient setting or at home. Prices of these cultures differ for negative (€ 30) and positive (€ 56) cultures. It takes 3 to 7 days before the results of these cultures are available. In this scenario, therefore, the ERCP population was divided into two groups. Patients in need of ERCP within 5 days were allocated for treatment with an SUD because their MDRO carriage status might not become available in time. Patients scheduled for their treatment beyond a horizon of 5 days underwent standard treatment using a reusable duodenoscope, unless they were MDRO-positive, at which time they were switched to an SUD. Additional analyses were performed considering the time to culturing results to be 3 or 7 days.

For crossover Scenario 2, the MDRO carriage can also be identified during working hours directly from the medium on a rectal swab sample by using GeneXpert analysis without the need for a culture. This method requires the availability of a GeneXpert device and is more expensive (at least € 103 per sample). It is somewhat less sensitive compared to standard cultures and cannot be used to detect extended-spectrum beta-lactamase-producing (ESBL) microorganisms, but provides results within a few hours. In this scenario, theoretically, it is possible to screen all patients for MDRO carriage who do not need a same-day ERCP. In this scenario, therefore, all patients who need an urgent ERCP within 24 hours are treated with an SUD. All other patients are screened for MDRO carriage and treated with a reusable duodenoscope if they are found to be MDRO-negative.

Data collection

This study included costs of duodenoscopes, disinfection, surveillance culturing, MDRO screening and treatment of DAIs. Costs for both materials and personnel were included. Not included were costs incurred independent of use of a single-use or reusable duodenoscope, such as use of the ERCP room, staff and specific instruments used during the ERCP procedure.

The costs of materials and staff were based on estimates from our own department at the Erasmus Medical Centre (Erasmus MC). Based on data from our endoscopy department, we estimated the costs of reusable duodenoscopes to be € 180 per procedure (▶ **Table 1**). This includes the purchase, maintenance and reprocessing costs and the costs for surveillance sampling of the duodenoscopes. In our institution, duodeno-



▶ **Fig. 1** Tree model with crossover scenario 1 next to current practice with only reusable duodenoscopes. Percentages represent chances in the Erasmus MC scenario. MDRO, multidrug-resistant organism; DAI, duodenoscope-associated infection.

▶ **Table 1** Breakdown of costs for reusable duodenoscopes in current situation in the Erasmus MC performing 900 ERCP procedures annually with a mean of eight reusable duodenoscopes.

	Price per duodenoscope	Price per ERCP procedure
Purchase	€39,309	€100
Maintenance	€2,500 (per year)	€22
Reprocessing	–	€47
Surveillance culturing	€110 (per surveillance moment)	€11
Total		€180

ERCP, endoscopic retrograde cholangiopancreatography.

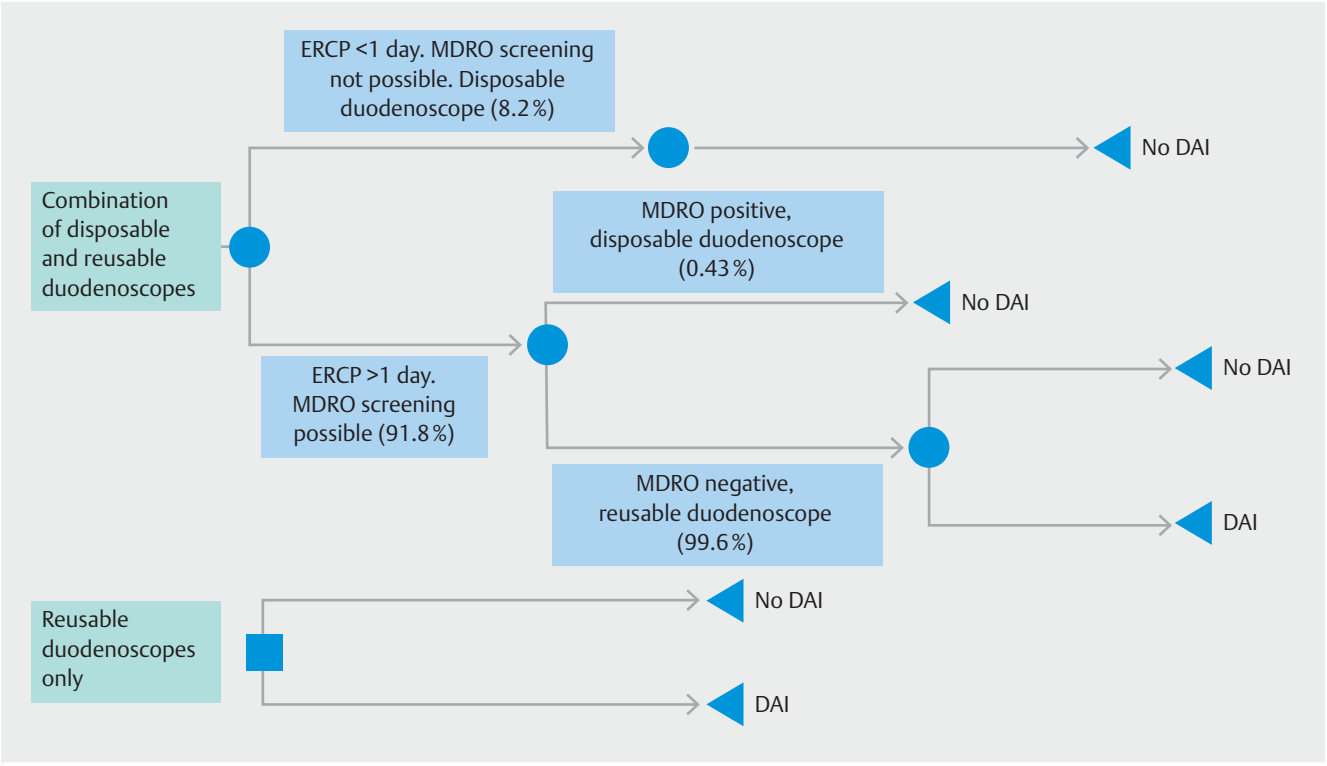
▶ **Table 2** Breakdown of costs for a duodenoscope-associated infection (cholangitis) in the Erasmus MC.

	Price	Number	Total
Day of hospitalization	€586	8.5	€4980
Chest X-ray	€52	1	€52
Abdominal ultrasound	€120	1	€120
ERCP procedure	€1,163	1	€1,163
Blood culture	€42	2	€84
Venous blood sample	€25	7	€172
Intravenous meropenem treatment	€16.94	12 (doses)	€203
Total			€6,774

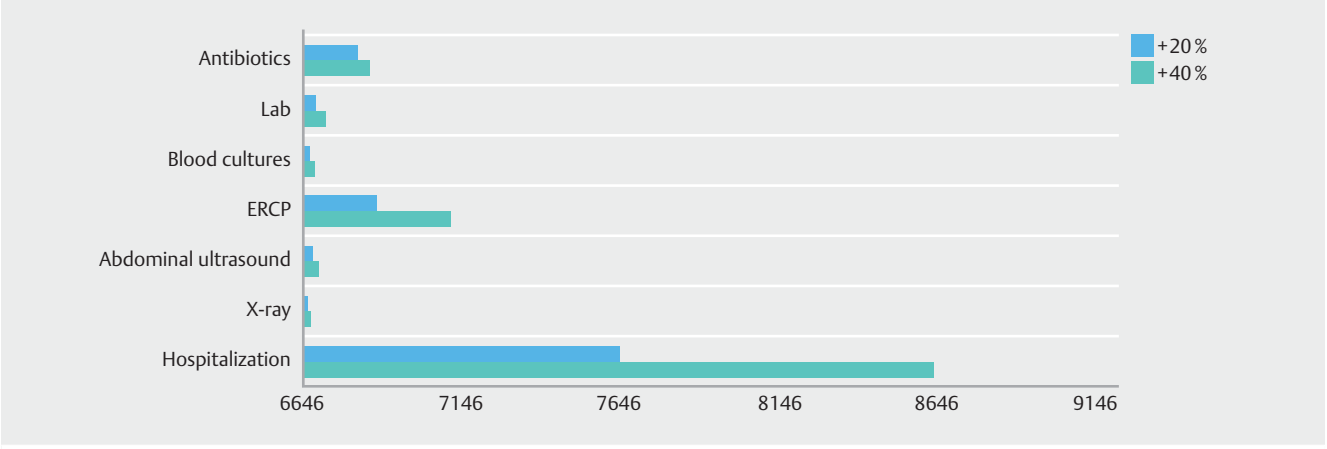
ERCP, endoscopic retrograde cholangiopancreatography.

scopes had a mean lifetime of 3.5 years, performing 394 ERCP procedures during their lifetime.

The costs for a DAI were calculated from an average post-ERCP cholangitis episode and adjusted for an infection with an ESBL microorganism. We defined the average treatment of such a post-ERCP cholangitis based on 42 cases found in an ERCP database of 610 ERCP patients treated in our center in 2015, which was initially used for other study purposes (data not published). Based on these cases, we found that the average cost for treatment of a DAI case amounts to €6,774 in our center, and that hospitalization days account for three-quarters of the expenditure (▶ **Table 2**). ▶ **Fig. 3** shows a sensitivity analysis for this DAI cost, investigating a 20 % and 40 % increase in the separate variables. From the same database we extrapolated that 57.3 % of ERCP patients at our department undergo their procedure at least 5 days after the initial order and 8.2 % undergo the procedure urgently within a day.



▶ **Fig. 2** Tree model with crossover scenario 2 next to current practice with only reusable duodenoscopes. Percentages represent chances in the Erasmus MC scenario. MDRO, multidrug-resistant organism. DAI, duodenoscope-associated infection.

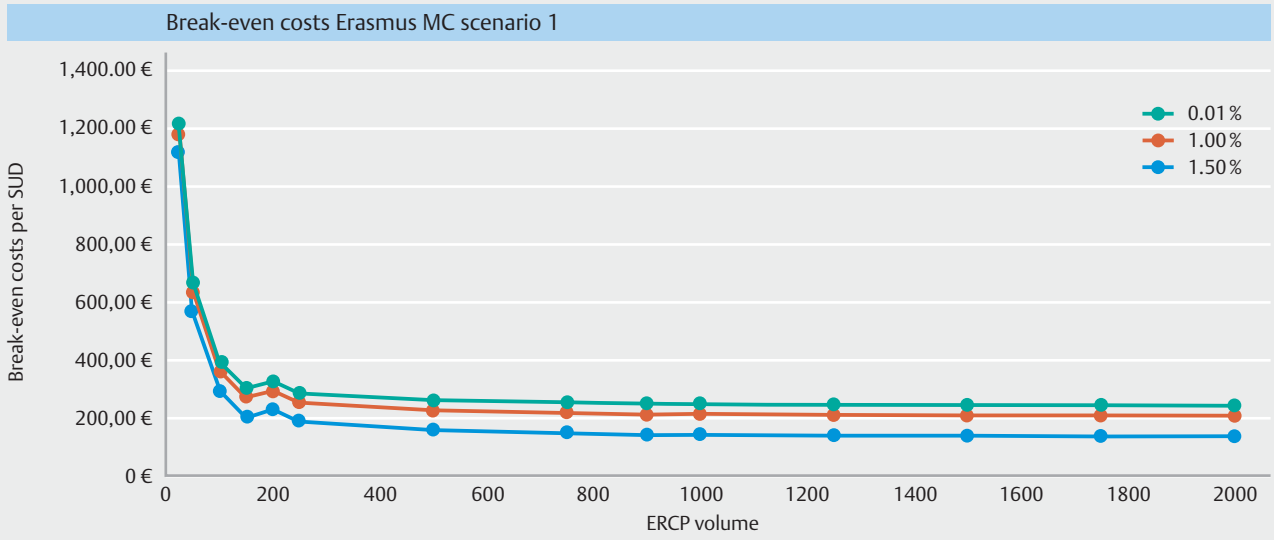


▶ **Fig. 3** Tornado diagram showing sensitivity analysis of DAI costs with a 20 % and 40 % increase of the separate variables included in the Erasmus MC.

Break-even analysis

Decision tree models (▶ **Fig. 1** and ▶ **Fig. 2**) involving the two crossover scenarios were made in Excel (Microsoft Office 2016). For both crossover scenarios, we calculated the maximum price of an SUD to financially break even with the current situation in which only reusable duodenoscopes are used. Calculations were done for an ERCP volume of 900 ERCPs/year, but also for ERCP volumes ranging from 25 to 2000 ERCPs/year.

In this break-even analysis, we only considered direct costs, which include the costs of the duodenoscopes, MDRO screening (through culturing or GeneXpert) and treatment of DAIs. In the models, these costs were imputed, including the chances of MDRO carriage, risk of a DAI and the proportion of patients being eligible to wait for MDRO screening prior to the ERCP procedure. A recent hospital-wide study in our institution found a prevalence of MDRO carriage of 4.3 % among hospitalized patients [14]. This includes methicillin-resistant *Staphylococcus aureus* (MRSA) and highly resistant *Pseudomonas aeruginosa, Acinetobacter baumannii, Enterococcus faecium,* and Enterobacterales. Excluding the ESBL-producing microorganisms, only



▶ **Fig. 4** Break-even costs (in Euros) per ERCP procedure based on three different DAI risks in the Erasmus MC, in crossover scenario 1. SUD, single-use duodenoscope

0.43 % carried MDROs. Because specific data for the ERCP population are lacking, we used this 4.3 % (Scenario 1) and 0.43 % (Scenario 2) prevalence in our break-even analysis. In the analyses we used three different DAI infection risks; a bare minimum risk of 0.01 % as we recently found in a systematic review based on DAI outbreaks in the Netherlands [3] and maximum risks of 1 % and 1.5 % as used in previously published US cost analyses [12, 13]. Indirect costs such as the costs of productivity losses were not included.

US cost analyses

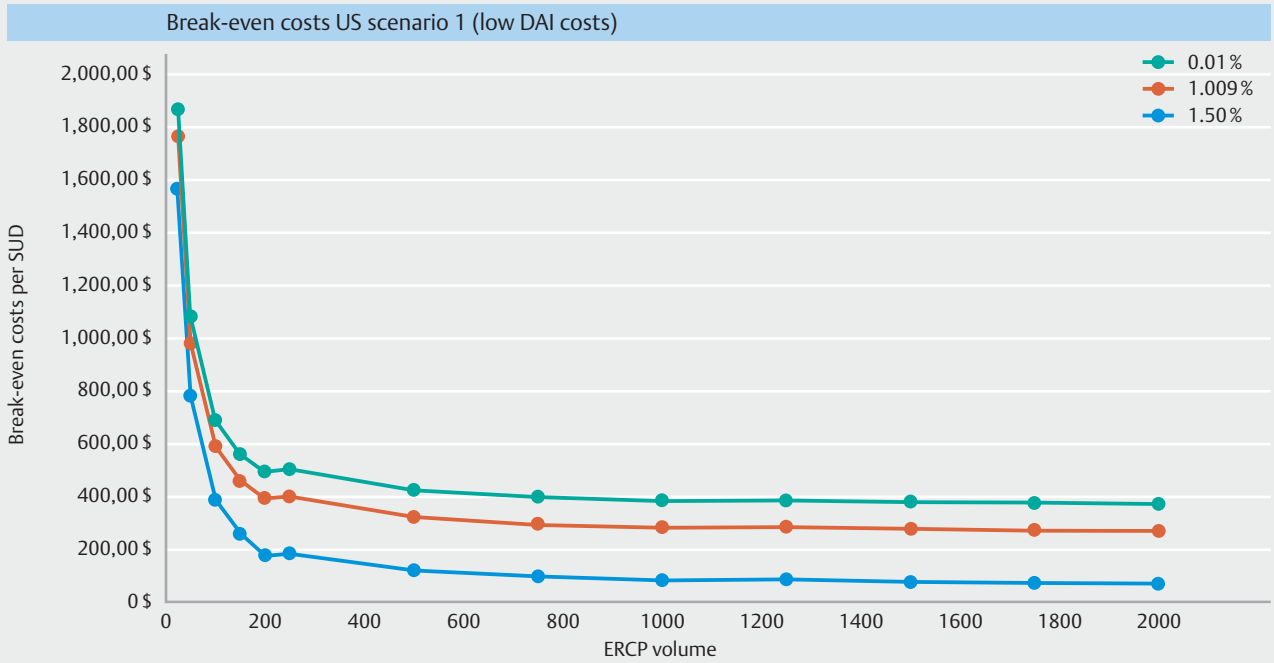
We performed the same break-even analyses for a US scenario. For this, we relied on public data regarding the US costs of reusable duodenoscopes, MDRO prevalence rates and US costs for treating patients with post-ERCP infection. An article by Bang et al. [12] was found comparing a practice with only reusable duodenoscopes to a practice in which only SUDs are used. We used their per-procedure costs for the use of reusable duodenoscopes (ranging from $109 to $1599) and added to that $11 for periodic culturing [15], considering surveillance is performed after approximately every 10 ERCP procedures. DAI treatment costs were based on the costs associated with bacterial infections as found in the HCUPnet database of 2020 to be $20,119 with an average hospital stay of 7.1 days [16]. An alternative analysis was performed using the charges ($78,756.00) found for treatment of the same bacterial infections. The charges for the same treatment are much higher than the actual costs because they represent the initial value hospitals use to start negotiations with insurance parties. Prevalence of MDRO carriage in these analyses was set at 11.3 %, as found in literature (including MRSA, carbapenem-resistant enterobacteriaceae [CRE] and vancomycin-resistant enterococci [VRE], but not extended spectrum beta-lactamase-producing microorganisms) [17, 18].

Results

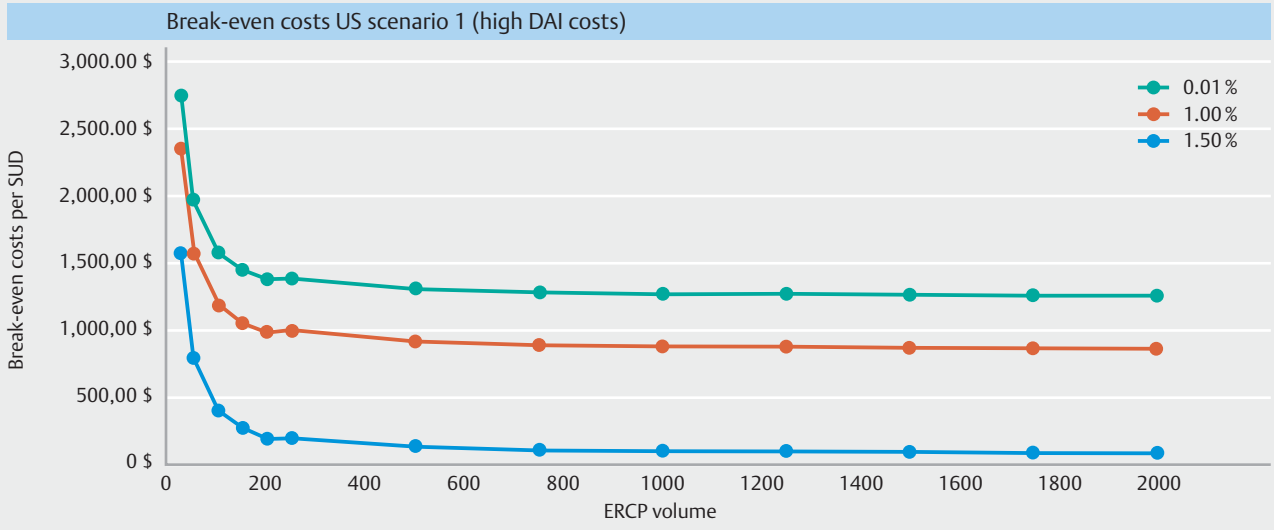
Break-even analyses for Dutch situation

In the Erasmus MC, delivering a yearly volume of 900 ERCP procedures, the break-even costs for SUDs in crossover Scenario 1 were found to be € 140, € 208, and € 242 for DAI risks of 0.01 %, 1.0 %, and 1.5 %, respectively (▶ **Fig. 4**). The ERCP volume is the most obvious parameter influencing the outcome up to a volume of approximately 250 procedures per year; after that, all curves flatten. For small-volume centers (≤ 50 ERCPs/year), break-even costs ranged between € 568.00 and € 1,218.16. In high-volume centers (≥ 150 ERCPs/year), break-even costs were found between € 135.46 (DAI risk 0.01 %) and € 302.75 (DAI risk 1.5 %). In crossover Scenario 2, due to the higher costs of MDRO screening with GeneXpert in a population with a relatively low MDRO prevalence, it was only possible to break even in the scenarios with the lowest ERCP volume (i. e., ≤ 50 ERCPs/year), with break-even costs ranging between € 54.02 and € 154.87.

In additional analyses of Scenario 1, the time needed to receive culture results was set at 3 or 7 days. It was found that changing this interval caused small changes in the break-even costs. Reducing the period to 3 days, meaning that hypothetically everybody in need of an ERCP within 3 days was treated with an SUD, and all patients able to wait at least 3 days were screened prior to the ERCP procedure, reduced the break-even costs by approximately € 23. Extending the period to 7 days caused an increase of the break-even costs per procedure of approximately € 10.



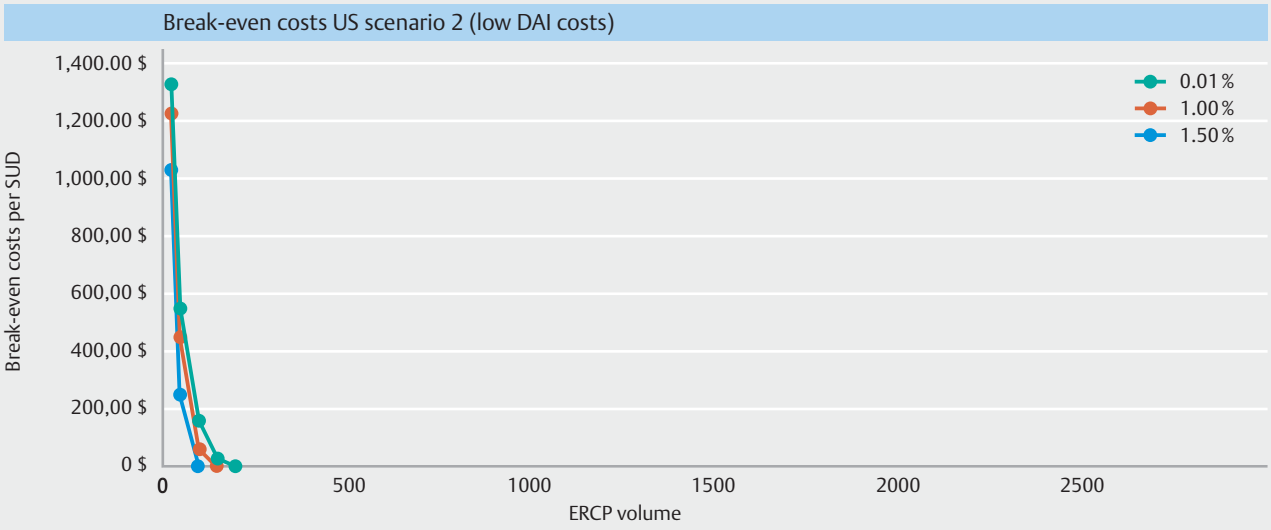
▶ **Fig. 5** Break-even costs (in US dollars) per ERCP procedure based on three different DAI risks in the US, in crossover scenario 1 using low DAI costs. SUD, single-use duodenoscope.



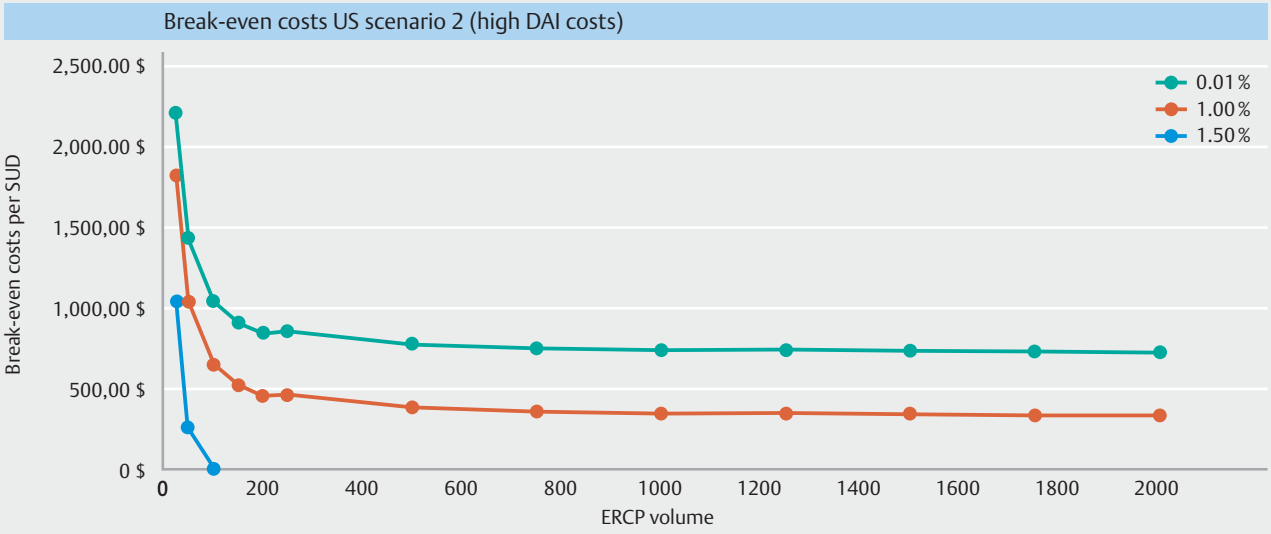
▶ **Fig. 6** Break-even costs (in US dollars) per ERCP procedure based on three different DAI risks in the US, in crossover scenario 1 using higher DAI costs. SUD, single-use duodenoscope.

Break-even analyses for US situation

Break-even costs in crossover Scenario 1, using the US data, are shown in ▶ **Fig. 5**. In low-volume centers (≤ 50 ERCPs/year), the break-even costs ranged between $787.21 (DAI risk 0.01 %) and $1,867.99 (DAI risk 1.5 %). For high-volume centers (≥ 150 ERCPs/year), these costs ranged between $78.21 (DAI risk 0.01 %) and $565.99 (DAI risk 1.5 %). When the DAI costs were changed to $78,756.00 (charges), the break-even costs in Scenario 1 for low-volume centers ranged from $793.08 (DAI risk 0.01 %) to $2,747.54 (DAI risk 1.5 %), as shown in ▶ **Fig. 6**. For high-volume centers, break-even costs ranged from $84.08 (DAI risk 0.01 %) to $1,445.54 (DAI risk 1.5 %). In crossover Scenario 2, using the lowest DAI costs, it was only possible to break even in low-volume centers (▶ **Fig. 7**). The break-even costs for



▶ **Fig. 7** Break-even costs (in US dollars) per ERCP procedure based on three different DAI risks in the US, in crossover scenario 2 using low DAI costs. SUD, single-use duodenoscope.



▶ **Fig. 8** Break-even costs (in US dollars) per ERCP procedure based on three different DAI risks in the US, in crossover scenario 2 using higher DAI costs. SUD, single-use duodenoscope.

low-volume centers ranged between $248.89 (DAI risk 0.01 %) and $1,329.70 (DAI risk 1.5 %). With the DAI costs changed to the higher charges, it was possible to break even in the scenarios with DAI risks of 1.0 % and 1.5 % (▶ **Fig. 8**). In low-volume centers, break-even costs ranged between $254.79 (DAI risk 0.01 %) and $2,209.23 (DAI risk 1.5 %). In high-volume centers, break-even costs ranged between $325.45 (DAI risk 1.0 %) and $907.23 (DAI risk 1.5 %).

Discussion

SUDs represent the ultimate answer to the problem of duodenoscope contamination and DAIs. The functionality of these SUDs has been found to be comparable to that of reusable duodenoscopes in simulation studies and clinical case and cohort studies. [19–22]. The current study is the first to evaluate costs associated with crossover strategies in which the use of SUDs is specifically targeted to known MDRO-carrying patients and patients with an unknown MDRO status. In our institution, we found that SUDs need to be priced at a maximum of € 140 to €242 to break even with the current practice with reusable duo-

denoscopes only. This price is 10 times lower than the currently known prices of SUDs and, therefore, is unlikely to become reality soon. In the field of single-use bronchoscopes, which were introduced into the market in 2009, prices have already fallen to a level at which single-use scopes eventually became cost-effective in comparison to reusable endoscopes [23]. Due to higher DAI costs and MDRO carriage rate, break-even costs may be substantially higher in other countries. This study showed that, in the United States, these break-even costs are higher than in the Dutch situation, but are still lower than the current list prices for the available SUDs, which are in the range of $1,400 to $2,900 [19, 24]. Importantly, the current evaluation only deals with a comparison of direct cost related to the endoscopy.

The break-even costs of the proposed strategies depend largely on ERCP volume, costs associated with a DAI and the chance of such a DAI. The ERCP volume determines how efficient an individual duodenoscope is used, and thus, what the costs of the instrument are per procedure. The costs of treating a DAI are country- and institution-specific. Here, we noticed large differences in these costs between the Erasmus MC (€6,774) and the US situation ($20,119) as found on HCUPnet [16]. However, literature shows a wide range of DAI costs in cost analyses comparing reusable duodenoscopes and SUDs. Barakat et al. [25] considered the costs of one DAI case to be $375,000 (including 2 days of care in an intensive care unit and 1 day in a step-down unit), and Travis et al. [13], who also used data from HCUPnet, considered a DAI case to cost $47,181. The DAI costs used in the break-even analysis have the most impact on the equation. This explains the variation in break-even costs found in this study compared to the ones of Bang et al. [12] and Travis et al. [13]. Furthermore, in the US situation, the actual costs of in-hospital treatment is much lower than the charges sent to the insurer. When these charges are used in break-even analyses instead of the actual costs, SUD prices can be much higher and still allow break even with reusable duodenoscopes.

DAI risk definition remains difficult because we have to rely on outbreak reports and reviews to estimate the actual risk of DAIs. Detection and reporting bias are likely to negatively influence a valid approximation of the DAI risk with 0.01 % being the absolute bare minimum risk based on literature reports concerning outbreaks in Dutch centers [3]. MDRO prevalence rates among patients in need of ERCP and the potential for a scope to become contaminated with an MDRO vary greatly throughout geographical regions, as is observed in the general population, but exact numbers are lacking [26]. In the Netherlands, MDRO carriage is relatively rare and consists mainly of colonization with ESBL-producing microorganisms and only incidentally with MRSA, CRE or VRE [26, 27]. In countries where ESBL-producing microorganisms are more prevalent, screening for carriage of these microorganisms is sometimes omitted. The MDRO prevalence rate used in the cost analyses for the US situation was also based on studies not involving ESBL carriage [17, 18]. Moreover, the GeneXpert method as used in crossover Scenario 2 is not capable of identifying ESBL-producing microorganisms, but only MRSA, VRE and CRE. Therefore, this scenario is only of interest in populations with a higher prevalence of MRSA, VRE, CRE and resistant *P. aeruginosa*.

The decision to switch completely or partially to SUDs should not be based only on the costs of the different scenarios. Some aspects pertaining to the value and impact of preventing DAIs and MDRO transmission through duodenoscopes should also be considered and are difficult to factor in from a financial viewpoint. Switching to SUDs will prevent DAIs caused by exogenous microorganisms. In a recent systematic review, Deb et al. found that over 77 % of all DAIs present as cholangitis or sepsis [28]. These infections have a major impact on the individual patient who requires re-hospitalization for treatment with antibiotics and often another ERCP procedure. However, individual post-ERCP infections might still occur due to translocation of endogenous microorganisms, which is not prevented by using SUDs. Our analyses only included direct costs (such as for materials and labor) and did not consider effects on patient quality of life. Furthermore, outbreaks with MDRO or non-MDRO DAIs are likely to cause much unrest among patients and generate negative publicity. In some instances, substantial financial claims were filed against institutions. A strategy that maximizes efforts to prevent such outbreaks is likely to reassure patients and prevent legal claims.

The observation that the prevalence of certain MDROs in the last few decades has risen in the general population [29] makes it even more relevant to prevent the spread of such microorganisms through medical interventions. A general advantage of SUDs is that next to prevention of MDRO transmission, spread of sensitive exogenous bacteria and viruses is prevented as well, making it the only sure way to abolish any risk of exogenous infections.

Besides the costs, the introduction of SUDs comes with challenges. First, more experience is needed to see whether they can deliver the same quality and patient outcomes as reusable devices. Preliminary in vitro studies and patient (cohort) studies have shown encouraging results [19–22]. Second, a complete switch to single-use devices requires an intensification in the supply chain and may cause storage issues. Third, the environmental impact is expected to increase due to the use of single-use endoscopes. Namburar et al. [30] found that replacing reusable duodenoscopes with SUDs increases the overall waste created by endoscopic procedures by 40 %. Moreover, Agrawal and Tang [31] describe the limited possibilities of recycling of SUDs. In light of the environmental crisis and global healthcare already being responsible for 4.4 % of global net emissions [32], increasing the climate footprint by switching to SUDs might pose a challenge. However, because the aforementioned argument is more one of ethics than economics, each community might appreciate and value this in a different way. Moreover, efforts are ongoing to increase the reuse of plastics used in the production of single-use endoscopes. There are even initiatives to investigate the use of biodegradable plastics in the production of single-use devices.

Limitations

The current cost analysis is primarily based on the situation in a large tertiary care academic center in the Netherlands. The costs for using reusable duodenoscopes differ greatly per institution depending on ERCP volume, contracts with manufacturers, organization of reprocessing, MDRO prevalence rates, the time span between setting the indication and the actual ERCP procedure and the time needed for testing MDRO carriage. Other factors, such as the costs associated with a DAI and the prevalence of MDRO carriage, are also likely to differ per institution. It remains important, therefore, that each institution makes its own judgment about whether partial or full conversion to single-use endoscopes is worthwhile.

In our analyses, costs were based on local averages, including an average lifespan and average number of procedures performed with one duodenoscope. These variables can differ per institution. For the US analyses, we depended on the details provided by HCUPnet and the article by Bang et al [12]. However, the most influential variable in the analyses, the DAI costs, is hard to estimate and large differences are found in the literature.

In this cost analysis, we chose specific crossover strategies in which SUDs are only used in MDRO carriers and patients ineligible to wait for screening results. However, other strategies to implement SUDs can be considered as well. For instance, they could also be used in immunocompromised patients to protect them from DAIs.

Conclusions

SUDs eliminate the risk of microorganism transmission from contaminated duodenoscopes into patients, and thus, eliminate the risk of DAIs. A complete switch from reusable to SUDs requires a substantial financial investment, not only because the per-procedure costs are likely to increase, but also because of early depreciation of the capital investment pertaining to reusable endoscopes.

This cost analysis showed that a crossover scenario in which SUDs are only used in MDRO-carrying patients and patients with unknown MDRO status could be an economically more viable alternative. For the Dutch situation, however, SUDs need to be priced much lower to come even close to a break-even point in comparison to the US situation.

Competing interests

The authors declare that they have no conflict of interest.

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